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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,482	08/28/2003	David Ron	05986/100L712-US1	7211
7278	7590	10/17/2005	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			GITOMER, RALPH J	
			ART UNIT	PAPER NUMBER

1655

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/650,482	RON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ralph Gitomer	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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The CRF submitted 9/5/03, the Power of Attorney received 11/9/04, the IDS and preliminary amendment received 3/22/04 have been entered and claims 1-33 are currently pending in this application.

On page 4 of the present specification, it is understood this invention involves the discovery of a GADD34 related regulatory subunit of PP1c, named GADD34L that is in some fashion distinct from GADD34. GADD34 is only expressed following oxidative stress induced activation of eIF2alpha kinases, not in cells not subject to stress, whereas GADD34L is expressed in cells not subject to oxidative stress and has the same function. There appears to be at least 99% homology between GADD34 and GADD34L. However, a search reveals only GADD34 was known and GADD34L may be novel. And it would appear that both GADD34 and GADD34L are regulatory subunits of eIF2alpha PP1c holophosphatase. How they may differ is queried.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-33 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Claims are 31-32 directed to preventing or treating a disease involving an oxidative stress by administering a substance identified by a method. Claims 1-30, 33 are directed to screening for compounds that prevent or treat a disease involving an oxidative stress and specify some broad categories of disease such as "a neurodegenerative disorder". The specification does not teach any substance

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administered and no evidence that any substance found by the claimed method would prevent or treat any disease. On page 37 of the present specification, a single compound is described found by the claimed method named 22P19 whose structure is found in Fig. 7 that inhibits GADD34L. The written description presented does not enable this compound for the functions claimed. The leap from identifying a possible compound involved in a known pathway to the presently claimed functions lacks credibility.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification as originally filed does not enable one of skill in this art to know which substance administered would prevent or treat any disease as claimed in claims 31-32. Further, if one did administer some compound for the claimed function, one would not necessarily know how it was identified. No written description is found for administering anything found by the claimed method of claims 1-30, 33.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

There are many instances of lack of antecedent basis in the claims that require correction, for example in claim 1 line 2, "the prevention", 1(i) "the activity" and many others. It is noted that compounds do not have abilities but activities. There may be typos in the claims regarding the alpha symbol, see claim 7(i) and others. In claim 29 preventing an autoimmune disease is queried.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ciaramella (EP 0 997 537 A2) teaches inhibiting GADD34.

JP 2005-130744 teaches promoting and suppressing GADD34 expression.

Brown (US 2004/0023872 A1) teaches using GADD34 regulation.

Ron (US 2003/0008272 A1) teaches preventing or treating disease by regulating GADD34.

Nagy (US 2003/0032673 A1) teaches treating AD, in paragraph 129 DNA damage and GADD34.

Fisher (US 2003/0219376 A1) teaches in paragraph 6, GADD34.

Brown (6,641,995 B2) teaches in column 2 lines 12 GADD34 and its homologues.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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